Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect Of Flaxseed Oil Supplementation On Long-Chain Fatty Acids, Lipid Profile, Arachidonoyl Ethanolamide Level And CB1/CB2 Expression In Patients With Coronary Artery Disease

Protocol summary

Summary

This randomized, double-blind, controlled clinical trial will be done on a total of 44 coronary artery disease (CAD) patients. Participants will be divided randomly into intervention and placebo groups. The CAD will be defined as presence of ≥1 stenotic coronary arteries with at least 50% stenosis confirmed by coronary angiography among subjects referring to Madani University hospital, Tabriz, Iran. The participants with 30-60 years old and BMI at the range of 25-35 will be included. Patients with other cardiovascular or chronic diseases will be excluded. To minimize the effect of confounders, matching will be applied for age, sex, BMI and any current anti-hyperlipidemic and anti-hypertensive medications . All the Subjects will be receiving a moderate calorie restricted dietary plan. They will be requested to consume 200 ml of milk prepared with 2.5% flaxseed oil (containing 2 g alpha linolenic acid) or skimmed milk for eight consecutive weeks. Food intake will be assessed using 3 days food record method at the beginning and end of the study. After 10-12 h fasting, 10 ml blood will be taken to evaluate primary outcomes including long-chain fatty acids, lipid profile, arachidonoyl ethanolamide and CB1/CB2 m-RNA expression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071211288N10**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name
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Name of organization / entity
Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Flaxseed Oil Supplementation On Long-Chain Fatty Acids, Lipid Profile, Arachidonoyl Ethanolamide Level And CB1/CB2 Expression In Patients With Coronary Artery Disease

Public title

Effect Of Flaxseed Oil In Coronary Artery Disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:angiographically confirmed coronary

artery disease with more than 50% stenosis of at least one of the major coronary vessels; subjects with 30-60 years old; BMI equal 20-30 kg/m2 Ę̣xclusion criteria:Miocardial infarction; Heart failure (function class III and IV), Heart valve diseases; Diabetes or any other chronic disease; Consumption of any immunosuppressive drugs; Antioxidant and/or vitamin supplements; Fish oil or (n-3) fatty acid supplements; Weight loss drugs or weight loss surgery; Smoking and drug users; Pregnant and lactating women; Those with Lactase deficiency(milk intolerance)

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Golghasht St, Tabriz University Of Medical Sciences

City
Tabriz

Postal code

Approval date
2016-10-10, 1395/07/19

Ethics committee reference number
IR.TBZMED.REC.1395.804

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease

ICD-10 code
I70

ICD-10 code description
Atherosclerosis

Primary outcomes

1

Description
Levels Of Long Chain Fatty Acids

Timepoint
Pre And Post Intervention

Method of measurement
Gas Chromatography

2

Description
Lipid Profile

Timepoint
Pre And Post Intervention

Method of measurement
Enzymatic Method

3

Description
Arachidonoyl Ethanolamide Level

Timepoint
Pre And Post Intervention

Method of measurement
HPLC

4

Description
CB1/CB2 m-RNA Expression Level

Timepoint
pre and post intervention

Method of measurement
Real Time PCR

Secondary outcomes

1

Description
Correlation Between Body Fat Percentage And Arachydonoylethanolamine Level

Timepoint
Pre and post intervention

Method of measurement
Bioelectrical impedanse for body fat and HPLC for arachydonoylethanolamine level

2

Description
Appetite And Depression Situation

Timepoint
Pre And Post Intervention

Method of measurement
Visual Analouge Scale and BECK questionnaires

3

Description
Energy And Macronutrient Levels
Timepoint
Pre And Post Intervention
Method of measurement
Food Record Questionnaire

4

Description
Physical Activity Level
Timepoint
Pre And Post Intervention
Method of measurement
International Physical Activity Questionnaire

Intervention groups

1

Description
200 ml Of Milk Prepared With 2.5% Flaxseed Oil (containing 2 g alpha linolenic acid)/day For 2 Months
Category
Lifestyle

2

Description
200 ml Of Skimmed Milk/Day For 2 Months
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital, Tabriz
Full name of responsible person
Dr. Mohammad Alizadeh
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Office Of The Vice Chancellor For Research Of Tabriz University Of Medical Sciences
Full name of responsible person
Dr. Rashidi
Street address
Vice – Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Office Of The Vice Chancellor For Research Of Tabriz University Of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty